K072023

510(k) Summary

Ellipse A/S

SEP 12 2007

Ellipse Juvia laser system

This *510(k) summary* is submitted in accordance with the requirements of 21 CFR Part 807.87(h) and Part 807.92.

A. Contact information and device identification:

Date of the summary:	20 July 2007
Submitted by/manufacturer:	Ellipse A/S Agern Alle 11 2970 Hoersholm, Denmark Tel: + 45 4576 8808 Fax: + 45 4517 6851
Contact person:	Ole Kofod
Device Trade Name:	Ellipse Juvia.
Device Model number:	9EJU7465.
Common Name:	Laser treatment system.
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810).
Device classification:	Class II.
Product code:	GEX
Predicate devices legally marketed to which Ellipse A/S claims equivalence:	• *Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device* (K022060) manufactured by Lumenis, Inc., Santa Clara, CA, USA. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)). • *SLIM Evolution Family of CO2 Lasers and Delivery Device Accessories* (K063001) manufactured by Lasering S.r.l, Modena, Italy. (Laser surgical instrument for use in general and plastic surgery and in dermatology (per 21 CFR Part 878.4810)).

B. Description of *Ellipse Juvia* system:

The Ellipse Juvia system comprises the following major parts:

- A laser console containing a CO_2 laser module capable of providing a laser beam having a wavelength of 10,600 nm.
- A scanner that is intended to manipulate and place a pulsed beam received from the laser console in a pre-specified pattern on the skin being treated.
- An optical fiber providing a beam path from the laser to the scanner.

C. Intended Use of *Ellipse Juvia* system:

Ellipse Juvia is intended for use in dermatology and plastic surgery for treatment of:

- Skin Resurfacing
- Wrinkles, Rhytides, and Furrows
- Acne Scars

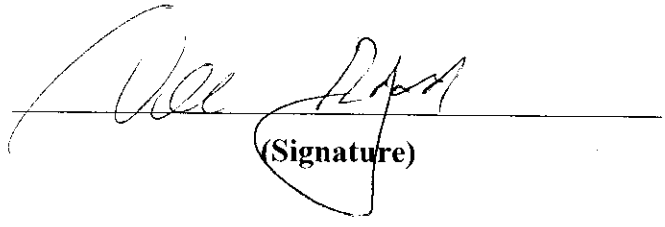
D. Comparison of *Ellipse Juvia* to predicate devices: for deep applications 0.15 – 2.5mm

Issue/data compared	Ellipse Juvia	SLIM (Lasering S.r.l)	Ultrapulse Encore (Lumenis)
FDA clearance / status	Being submitted (this submission)	K063001	K022060
Indications	Skin resurfacing, wrinkles, rhytids, and furrows, acne scars	Skin resurfacing, treatment of furrows and wrinkles, acne scars, and others	Skin resurfacing, wrinkles, rhytids, and furrows, acne scars, and others
Technology	The system comprises: a) A laser console containing a CO2 laser module b) A scanner for producing a pattern of light spots on the skin c) a beam delivering system connecting the laser console and the scanner.	The system comprises: a) A laser console containing a CO2 laser module b) A scanner for producing a pattern of light spots on the skin c) a beam delivering system connecting the laser console and the scanner.	The system comprises: a) A laser console containing a CO2 laser module b) A scanner for producing a pattern of light spots on the skin c) a beam delivering system connecting the laser console and the scanner.
Length of beam delivering system	165cm	130cm	150 / 180 cm depending on model
Type of beam delivering system	Fiber providing full freedom of movement	Articulated arm with 340° of freedom	Articulated arm with 360° of freedom
Wavelength	10,600nm	10,600nm	10,600nm
Max power	0.11-20W ←	0.1-15W, 0.2-30W, 1-50W depending on the model	1-60W
Minimum scanner spot size	Ø300µm	Ø400µm	Ø1300µm
Max power density (computed as max power divided by minimum scanner spot size)	20W / Ø300µm = 28.6kW/cm2	15W / Ø400µm = 15.0kW/cm2 30W / Ø400µm = 30.0kW/cm2 50W / Ø400µm = 50kW/cm2	60W/ Ø1300µm = 6kW/cm2
Aiming beam	635nm, max 5mW	635nm, max. 2mW	635nm, max 5mW
Scanning speed (light spots on the skin per second)	0.3-100 Hz	1 –10,000 Hz	1-1,000 Hz
Time for a full scan	In the range of 1 sec – Actual time is depending on scan pattern chosen	In the range of 1 sec – Actual time is depending on scan pattern chosen	In the range of 1 sec – Actual time is depending on scan pattern chosen
Beam activation	Foot switch	Foot switch	Foot switch

Conclusion:

Ellipse Juvia applications and indications are evaluated to be within the scope of the previously cleared devices. The same counts for the essential treatment parameters, the protective conditions for the skin during treatment, and the working conditions of the physician.

Based on this side-by-side comparison of the overall performance characteristics of the predicate devices under consideration Ellipse A/S concludes that no significant differences exist. The Ellipse Juvia should not raise any new issues of safety and effectiveness and is judged to be substantially equivalent to the mentioned predicate devices.



(Signature)

Ole Kofod

(Typed Name)

20-July-2007

(Date)

(Premarket Notification 510(k) Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ellipse A/S
% Ole Kofod
QA/RA Manager
Agern Alle 11
DK-2970 Hørsholm
Denmark

SEP 12 2007

Re: K072023
Trade/Device Name: Ellipse Juvia
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 31, 2007
Received: September 7, 2007

Dear Ole Kofod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification

Device Name: **Ellipse Juvia**

Indications for Use:

Ellipse Juvia is intended for use in dermatology and plastic surgery for treatment of:

- Skin Resurfacing
- Wrinkles, Rhytides, and Furrows
- Acne Scars

(Signature)

Ole Kofod
(Typed Name)

20-AUG-2007
(Date)

K072023
(Premarket Notification 510(k) Number)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X__
(Per 21CFR 801.109)

OR

Over-The-Counter Use____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072023